A14752 - High Priority Medical Device Alert

Medical Device Ongoing Action
Updated: October 7, 2010
UMDNS Terms:
- Defibrillator/Pacemakers, External [17882]
- Defibrillators, External, Manual [11134]

Suggested Distribution:
- Cardiology/Cardiac Catheterization Laboratory
- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Nursing
- OR/Surgery
- Home Care
- EMS/Transport

Geographic Regions:
- (Impact in additional regions has not been identified or ruled out at the time of this posting)
- U.S.

Physio-Control—LIFEPAK 12 Defibrillator/Monitors: Failure to Follow Operating Instructions When Disconnecting Unit from AC Power May Result in Failure to Charge and/or Failure to Initiate Pacing

Product Identifier:
LIFEPAK 12 Defibrillator/Monitors *[Capital Equipment]*
Customers who purchased an AC power adapter and have a LIFEPAK 12 with a specific version of a power printed circuit board assembly (PCBA) are affected. The letter described below was sent only to these customers.

Manufacturer: Physio Control Inc Div Medtronic Inc [452575], 11811 Willows Rd NE PO Box 97006, Redmond, WA 98073-9706, United States
Problem: In an October 2010 Urgent Medical Device Information letter submitted by an ECRI Institute member hospital, Physio-Control states that it has received reports suggesting that users are not always following the operating instructions for disconnecting the above defibrillator/monitors from AC power. If the "Power ON" button is pushed within 2 sec after the device is disconnected from AC power, the service indicator will illuminate and the device may fail to charge the defibrillator and/or fail to initiate pacing. If this occurs, the device will not deliver a shock until the operating instructions are followed and the power is cycled off and then on again.
Action Needed: Verify that you have received the October 2010 Urgent Medical Device Information letter from Physio-Control. Identify any affected product in your inventory. Physio-Control states that no corrective or preventative actions are in place for this problem. The purpose of the notification is to ensure that users are aware of the problem and that they operate the defibrillator/monitors according to the current operating instructions. Instructions advise the user to wait 2 sec to push the "Power ON" button after disconnecting the device from AC power. If the button is pushed within 2 sec after the device is disconnected from AC power and the service indicator illuminates, turn the device off and then back on to restore full functionality. Operating instructions explain that if the service indicator comes on after the device is disconnected from AC power, you may continue to use the defibrillator if needed; however, turning it off and then back on may clear the service condition. If the service light remains on, remove the defibrillator from use and contact your Physio-Control local service representative. For complete operating instructions, visit Physio-Control's Website.

For Further Information:

Geographic Location:	Contact:	Telephone No.:	Website:
U.S.	Physio-Control technical support team	(800) 442-1142 (select option 5), from 6 a.m. to 4 p.m. Pacific time, Monday through Friday	Click here
Outside the U.S.	Physio-Control local representative		

Source:
- Letter submitted by ECRI Institute member hospital.
- Manufacturer.

Comment:
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.

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- The manufacturer has not confirmed the geographic distribution of affected product. ECRI Institute recommends that you check your inventory for this product regardless of where you are located.

Verification History: One Member Submission[10/4/2010 3:50:56 PM]; Alert Confirmed by Mfr./Dist.[10/7/2010 11:42:35 AM]; Fully verified[10/7/2010 11:42:37 AM]

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